

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D—0202]

DDM

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Certifier	R. LEDESMA

Draft Guidance for Industry on Bar Code Label Requirements—Questions and Answers; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Bar Code Label Requirements—Questions and Answers.” FDA regulations require certain human drug and biological products to have on their labels a linear bar code that identifies the drug’s National Drug Code (NDC) number. We have received several inquiries about how the requirements apply to specific products or circumstances. The purpose of the draft guidance is to respond to the questions.

DATES: Submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send

one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

For products regulated by the Center for Drug Evaluation and Research:

Michael D. Jones, Center for Drug Evaluation and Research (HFD-5), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

For products regulated by the Center for Biologics Evaluation and Research:

Elizabeth Callaghan, Center for Biologics Evaluation and Research (HFM-370), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3424.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Bar Code Label Requirements—Questions and Answers.” Under FDA regulations, certain human drug and biological product labels must have a bar code containing the drug’s NDC number (69 FR 9120, February 26, 2004). Bar codes will help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time.

This draft guidance is intended to explain certain bar code labeling requirements and their application to human drug and biological products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on certain questions and answers on bar code labeling requirements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.fda.gov/ohrms/dockets/default.htm>.

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Jeffrey Shuren,
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